

7073698

510(k) SUMMARY

Submitter:

Parkell, Inc.
300 Executive Drive
Edgewood, NY 11717
TEL: 631-249-1134
FAX: 631-249-1242

MAR 19 2008

Contact:

Daniel R. Schechter, Esq.
General Counsel
Parkell
300 Executive Drive
Edgewood, NY 11717

Submission Date:

28 December 2007

Trade Name:

SEcure

Common Name:

Dental Cement

Classification Name:

Dental Cement

Equivalence:

TOTALBOND, MAXCEM, UNICEM

Description/Intended Use:

SEcure is a dual-cure, self-etching, adhesive dental cement system consisting of a self-etching primer and a two-part dental cement. The self-etching primer is supplied in a single bottle, while the dental cement is supplied in a double-barrel auto-mix syringe. The cement system does not require acid etching of tooth surfaces, and can be cured with any available curing light. The intended use of SEcure is for indirect cementation of porcelain, ceramic, resin and metal-based inlays, onlays, crowns, bridges, veneers and posts.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2008

Mr Daniel R. Schechter, Esq.
Parkell, Incorporated
300 Executive Drive
Edgewood, New York 11717

Re: K073698

Trade/Device Name: SEcure Adhesive Dental Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: December 28, 2007
Received: December 31, 2007

Dear Mr. Schechter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

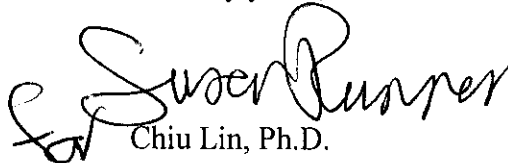
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", is written over the typed name.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073698

Device Name: SEcure Adhesive Dental Cement

Indications for Use:

SEcure Adhesive Dental Cement is a dual-cure, self-etching, adhesive dental cement system. It is intended for indirect cementation of porcelain, ceramic, resin, and metal-based inlays, onlays, crowns, bridges, veneers and posts.


Prescription Use X
(21 CFR Part 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Page 1 of 1

510(k) Number: K073698